

## REMARKS

Applicants respectfully request reconsideration of the present application.

### 1. Disposition of the Claims and Specification

Claims 44-62 are currently pending. Claims 44-51, 54, 58-59 and 61-62 are currently under consideration. Claims 52-53, 55-57 and 60 have been withdrawn. Claims 1-43 are canceled. Claims 44, 51 and 61-62 are amended. Support for the amendments to claims 44, 51 and 61-62 may be found in the specification, for example, at page 27, line 19.

Because the foregoing amendments do not introduce new matter and are made to clarify the scope of the claims, entry thereof by the Examiner is respectfully requested. Applicants believe that the amendment places the application in condition for allowance.

### 2. Claim Rejections – 35 U.S.C. §§ 101 and 112, first paragraph

Claims 44-51, 54, 58-59 and 61-62 are rejected under 35 U.S.C. § 101 for the reasons of record set forth in the previous office action. Applicants previously argued that the claimed protein has a function with biological significance based on Sugimoto *et al.* and Hsu *et al.* Specifically, applicants argued that the claimed protein (which is identical to p34SEI1 and TRIP-Br1) antagonizes p16INK4a, which inhibits CDK4 and CDK6, as well as regulates E2F-1/DP-1 transcriptional activity.

The examiner responded by saying that this specific function, described in the post-filing date articles, is not recited in the instant specification. The examiner reasons that there “is no demonstration of the biological function of the instant protein” in the specification; however, the examiner does admit that the specification provides “an assertion that the protein has homology to cell cycle regulation proteins (page 3, lines 2-28).” Office Action at 3. The examiner further admits that the specification discloses that “expression of CECRP is closely associated with cell proliferation.” Office Action at 3. The examiner asserts, however, that “bleach or gasoline are reagents that can affect cell proliferation.” Office Action at 3.

In referring to the list of diseases recited on page 40 of the specification, the examiner further reasons that Applicants “have failed to recite a specific and substantial utility for this particular protein because Applicants have failed to disclose a nexus between the expression of the claimed protein and any of these conditions” ranging from “cirrhosis, heart disease and infections.” Office Action at 3. Therefore, Applicants are claiming diagnosis of unrelated diseases using the polynucleotide encoding the instant protein.” Office Action at 3. The examiner concludes by stating that because Applicants have not established “any connection or correlation of the asserted protein with any particular disease or disorder, the assertions cannot be considered credible.” Office Action at 3.

***The Claimed Protein is Useful in the Diagnosis of, Treatment and/or Prevention of Ovarian Cancer***

Applicants respectfully disagree with the examiner. As the examiner has already pointed out, the specification discloses that the claimed CECRP protein is associated with cell proliferation by virtue of the fact that it is a cell cycle regulation protein. See page 3, lines 6-25. Accordingly, the examiner’s assertion that such utility and function is non-specific because bleach and gasoline are two of many examples of reagents that can affect cell proliferation is unfounded.

Applicants further disagree with the examiner’s statement regarding the lack of nexus between expression of the claimed CECRP protein and “any of the[] conditions” recited on page 40 of the specification. As explained above, Applicants have asserted that the claimed CECRP protein is associated with cell proliferation. As such, the expression of the claimed protein would specifically relate to the types of cancer listed in the specification at page 40, lines 7-11.

As further support, Applicants also refer to Tang *et al.*, “Identification of a Candidate Oncogene SEI-1 within a Minimal Amplified Region at 19q13.1 in Ovarian Cancer Cell Lines”, CANCER RESEARCH 62: 7157-7161 (2002), attached as Exhibit 1. This article confirms that SEI-1 is “associated with cell proliferation and cell cycle control.” Tang *et al.* at page 7159. The article also describes the finding that SEI-1 is overexpressed in ovarian

cancer cell lines and that it is a candidate oncogene with a role “in the development and progression of ovarian cancer.” Tang *et al.* at pages 7159-60. Along these lines, Applicants note that the instant specification discloses the use of the claimed protein in the treatment or prevention of ovarian cancer (page 27, lines 24-25 and 30-31) as well as in the diagnosis of ovarian cancer (page 40, lines 2-3 and 10). Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

**3. Claim Rejections – 35 U.S.C. §§ 101 and 112, first paragraph**

The examiner has also rejected claims 44-51, 54 and 58-59 and 61-62 under 35 U.S.C. § 112, first paragraph because the claimed invention is not supported by either a substantially asserted utility or a well established utility, for the reasons set forth with respect to 35 U.S.C. § 101.

Applicants respectfully disagree with the examiner. Applicants have established a specific and substantial asserted utility, as described above in Section 2. Therefore, Applicants respectfully request withdrawal of this rejection.

**4. Claim Rejections – 35 U.S.C. § 112, first paragraph**

Claims 44, 51 and 61-62 are rejected by the examiner under 35 U.S.C. § 112, first paragraph. The examiner asserts that the “at least 95% identical” limitation “still fails to adequately describe and enable an isolated protein that is at least 95% identical to the polypeptide of SEQ ID NO: 3.” Office Action at 5. The examiner reasons that “Applicants do not teach which regions of said polypeptide are critical to encode a functional polypeptide.” March 18, 2004 Office Action at 7. The examiner further states that the “specification does not provide the requisite examples ... that would allow the skilled artisan to produce a polypeptide having at least [95%] sequence identity of SEQ ID NO: 3, nor does the disclosure provide criteria that explicitly enable such critical features.” March 18, 2004 Office Action at 7.

Applicants respectfully disagree with the examiner. Table 2 of the instant specification recites various structural and functional fragments of SEQ ID NO: 3 such as (1)

potential phosphorylation sites (at S44, S60, S98, S117, S123, S180 and T73) and (2) identifying sequences and/or structural motifs such as the inhibin beta chain signature sequence. Applicants believe that Table 2 accordingly discloses those structural elements that are critical to encoding a functional polypeptide. As such, a skilled artisan would be able to create functionally equivalent 95% identical polypeptides by following the teachings of the specification. Specifically, by using the information from Table 2, one of ordinary skill would know to retain those portions of the sequence identified in Table 2 when creating a variant 95% identical to SEQ ID NO: 3. Applicants respectfully request reconsideration and withdrawal of the rejection.

**5. Claim Rejections – 35 U.S.C. § 112, second paragraph**

Claims 44-51, 54, 58-59 and 61-62 are rejected under 35 U.S.C. § 112, second paragraph. The examiner reasons that the metes and bounds of the term “cell cycle regulating activity” are unclear. The examiner also states that the term “regulates cell proliferation” is indefinite because it is unclear whether the claimed polypeptide attenuates or exacerbates cell proliferation.

Applicants respectfully disagree with the examiner. Applicants believe that the term “regulates cell proliferation” is clearly defined in the specification so that a person of ordinary skill in the art would understand the metes and bounds of the term. *See, e.g.,* page 27, lines 18-23, and at page 29, line 7, where it states that CECRP can be “an inhibitor of cell proliferation” as well as “a promoter of cell proliferation.” However, to expedite prosecution, Applicants have amended claims 44, 51 and 61-62 to clarify that the claimed polypeptide “promotes cell proliferation.” Support for the amendment to claims 44, 51 and 61-62 may be found in the specification, for example, at page 27, line 19. Applicants respectfully request reconsideration and withdrawal of the rejection.

**6. Conclusion**

Applicants believe that the present application is in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

It is acknowledged that the foregoing amendments are submitted after final rejection. However, because the amendments do not introduce new matter or raise new issues, and because the amendments either place the application in condition for allowance or at least in better condition for appeal, entry thereof by the Examiner is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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